Indian Journal of Traditional Knowledge
Vol 19(3), July 2020, pp 563-567

Clinical evaluation of *Tukhm-e-Sambhalu* (*Vitex negundo* Linn. seed) in *Usr-e-Tams Ibtedayee* (primary dysmenorrhoea)

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Received 11 October 2018; revised 13 July 2020

Primary dysmenorrhoea is painful menstrual cramps of uterine origin during menstruation without any identifiable pathological lesion. It is commonly seen in menstruating and lasting 12-24 h. Its prevalence is wide, as more than 70% of teenagers and 30-50% of menstruating women suffer from varying degree of discomfort. *Tibbe-e-Unani* claims to possess safe and effective therapeutic substances which are commonly prescribed in the management of primary dysmenorrhoea (*Usr-e-Tams Ibtedayee*), but despite being used in the treatment successfully, most of them have yet not been studied scientifically. Therefore, an attempt has been made in the present study to evaluate a single Unani drug *Tukhm-e-Sambhalu* (*Vitex negundo*) on 30 patients for its efficacy in primary dysmenorrhoea. The patients were administered test drug in powder form (5 g), by oral rout, twice a day for 7 days, starting 2 days before the onset of menstruation up to 5th day of menses, for three consecutive cycles. The important clinical features like pain in suprapubic region, pain in thigh, backache and headache were significantly reduced in patients treated with test drug. Thus, findings of this study suggested that *Tukhm-e-Sambhalu* is safe and effective in ameliorating the disease primary dysmenorrhoea.

Keywords: Primary dysmenorrhoea, *Tukhm-e-Sambhalu*, *Usr-e-Tams Ibtedayee, Vitex negundo*

IPC Code: Int. Cl.[20]: A61K 9/00

Dysmenorrhoea (*Usr-e-Tams*) means painful menstruation[1]. It is derived from the Greek word Dys, meaning difficult/ painful/abnormal; mens meaning month and rrhoea meaning flow[2]. Dysmenorrhoea may affect more than half of menstruating women[3,4]. In classical Unani literature, it has been described that *Usr-e-Tams* (dysmenorrhoea) is a variety of *Waja-e-Rahem* (uterine pain) that causes due to menstruation[5]. It also for their families and health sciences[6]. It is a major cause of absenteeism from work thus decreasing efficiency and quality of life among the affected women[7,8]. It is a common gynaecological complaint[9], with severe painful cramping sensation in the lower abdomen. It is often accompanied by other associated symptoms including sweating, tachycardia, headache, nausea, vomiting and diarrhoea, all occurring before or during the menstruation[10]. It is of two types. The pain which is of uterine origin and directly linked to menstruation but with no visible pelvic pathology, is known as primary (*Ibtedayee*) or true dysmenorrhoea and pain which is associated with pelvic pathology, is said to be secondary (*saanwi*) dysmenorrhoea[1].

Primary dysmenorrhoea (*Usr-e-Tams Ibtedayee*) is a common gynecological complain. It is painful menstrual cramps of uterine origin during menstruation without any identifiable pathological lesion[6,11-13]. It rs of menarche, when ovulatory cycles are established. This disorder affects the younger females but may persist into the 40s[11]. It affects more than 50% of post pubescent stage in women of 18-25 years of age groups. It is common in adolescent and characterized by spasmodic pain beginning with onset of menstruation and lasting 12-24 h. It is prevalent widely, as more than 70% of teenagers and 30-50% of menstruating women experience from varying degrees of discomfort. Only about 5-15% of populations are affected by severe incapacitating type which interferes with women's daily activities[3]. The pain arises in uterus and it is related to muscle

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contraction and colicky in type. It is felt mainly in hypogastrium and often referred to inner and front aspects of thighs[12]. Other symptoms are uterine cramping, nausea, vomiting, backache, diarrhea, giddiness, syncope and fainting. Now, it is very clear that pathogenesis of menstrual pain is attributable to biochemical derangement[3]. Prostaglandins and arachidonic acid metabolites have an important role in the development of dysmenorrhoea[6]. Women of primary dysmenorrhoea were shown to have higher level of prostaglandin (PG) of endometrial and menstrual fluid than those women without this problem. Prostaglandin acts directly on myometrium (uterine musculature) to increase basal intrauterine pressure and intensity and frequency of myometrial contraction. They also cause contraction of uterine arteries with tissue ischemia and pain. Finally, PGE2 may increase the sensitivity of peripheral pain fibers[14]. For the action of prostaglandin, the endometrium has to prime by estrogen followed by progesterone. That is why primary dysmenorrhoea is usually experienced in ovulatory cycles[1].

In spite of high prevalence of primary dysmenorrhoea, the choice of management available in western medicine is very less. Even the substances available for the purpose are not without side effects. The disease is usually treated with prostaglandin synthetase inhibitor (NSAID) and oral contraceptives that possess their own side effects such as headache, peptic ulceration, gastric irritation, erosion, chronic renal failure, hepatic failure, bleeding, skin rashes, asthma, weight gain, hypertension, vascular complications etc[15]. This situation justifies some alternative layout for the management of primary dysmenorrhoea. Unani medicine claims to possess effective and safe substances which can be therapeutically used in the management of *Usr-e-Tams Ibtedayee*, but they have not been scientifically evaluated on scientific parameters. *Tukhm-e-Sambhalu* (*Vitex negundo* Linn. seed) is one such drug which possesses *musakhkhin*, *mudirr-e-haiz*, *mulaiyan*[16], *mohallil*, *musakkin*[17], *mulattif* and *qabiz*[18] properties and described to be effective in *Usr-e-Tams*[19]. Therefore, a scientific study has been designed to evaluate possible efficacy of this drug in participants diagnosed with conformity to be suffering from *Usr-e-Tams Ibtedayee*.

Methodology

The women visited the OPD of Department of Ilmul Qabalat wa Amraz-e-Niswan, Mohammadia Tibbia Collage and Assayer Hospital, Mansoora, Malegaon, during 2014-2016, were screened for the *Usr-e-Tams Ibtedayee* (primary dysmenorrhoea) based on clinical signs and symptoms.

After taking the informed consent, 60 patients of reproductive age group (14-37) diagnosed with this disease were involved in this study. They were enlightened about this disease, examination performed and treatment given. The women suffering from any organic pelvic pathology, metabolic and hormonal disorders, sensitivity to NSAID and any systemic diseases like hypertension, diabetes mellitus and sexually transmitted diseases, were eliminated from this study. Prior to the initiation of this clinical study, permission from Institutional Ethics Committee (IEC) was obtained. With the help of computer randomized tables/ numbers, the patients were divided (Table 1) into two groups of 30 cases each. The patients in group of standard control (group I), were treated with one Tab Combiflam (Paracetamol 325 mg + Ibuprofen 400 mg), two times a day after meal orally, from starting of menstruation up to 3 days, for three successive menstrual cycles, to compare the study. While the women in group II (test group), were administered with powder of *Vitex negundo* Linn seed (*Tukhm-e-Sambhalu*), in a dose of 5 g, orally twice a day for one week, starting earlier 2 days of menstrual period up to 5th day of menses, for three consecutive cycles. The test drug was obtained from local traders, dehydrated at room temperature and reduced to course powder by grinding.

The patients were advised for follow up before and after each menstrual period of the cycles during treatment. The changes in clinical features of all the patients were documented for evaluation. At each visit patients were cautiously interrogated and their statements about the painful menstruation, pain in suprapubic region, pain in thighs, backache, nausea or vomiting, diarrhoea, headache and syncope/fainting were recorded.

Certain investigations such as HB%, TLC, DLC, ESR, random blood sugar, blood urea, serum creatinine, SGOT, SGPT, alkaline phosphatase, VDRL, Pelvic USG, urine & stool examination and

Table 1 — Treatment Schedule

Group	Drug Treatment	Dose	Duration
Group I	Tab. Combiflam (Paracetamol 325 mg + Ibuprofen 400 mg)	1 Tablet x BD	3 Days x 3 Menstrual cycle
Group II	*Tukhm-e-Sambhalu* powder	5 gm x BD	7 Days x 3 Menstrual cycle

pap smear in selected cases were done to establish the safety of the drug and to exclude the patients other than primary dysmenorrhoea. These investigations were carried out before starting and after stopping the treatment.

On every follow up all the symptoms and signs were sorted on point scales and changes were documented in case record form. The findings were recorded on a computerized proforma. Lastly, recorded observations were statically analyzed by chi square test.

Results and discussion

The efficacy of test drug in primary dysmenorrhoea was explored by observing clinical features. The observations were recorded, analyzed and compared with the standard drug (Table 2). Prior to the treatment pain in suprapubic region was observed in all (100%) the cases involved in the study, whereas after medication it was significantly reduced and persisted only in 36.66% and 53.33% of the cases and recovery was recorded in 63.33% and 46.66% of the case in group I and group II, respectively. Pain in the thigh on day of registration was recorded in 80% and 86.66% of the case in group I and II, respectively, while after therapy it has significantly decreased to 33.33% and 42.30% of the case and recovery was noted in 66.66% and 57.69% of the case, respectively. Before the treatment backache was noted in 76.66% and 86.66% in the group I and II, while after medication it has significantly decreased and remained only in 21.73% and 42.30% of patient and recovery was recorded in 78.26% and 57.69% of the case in group I and II, respectively. Before the therapy headache was recorded in 16.66% and 10% of case in group I and II, respectively, while after medication it has significantly reduced and totally disappeared in both the groups. On the day zero, Nausea/vomiting was observed in 6.66% and 13.33% of the case in group I and II, respectively, while after therapy it has significantly decreased and noted only in 50% and 25% of patient and recovery was recorded in 50% and 75% of case in group I and II, respectively. Prior to treatment syncope was observed in 3.33% and 6.66% of case in group I and II, respectively. While after medication it has significantly decreased and disappeared completely and 100% recovery was noted in group I but in group II, it was reduced to 50% and improvement was observed in 50% of the patients.

The findings of present study discovered that *Tukhm-e-Sambhalu* (*Vitex negundo* Linn. seed) is beneficial in relieving the symptoms and signs of *Usr-e-Tams Ibtedayee* (primary dysmenorrhoea), that is proved by decreasing suprapubic regionpain, thighpain, backache and headache. It was observed that all the parameters significantly recovered advocating that oral intake of *Vitex negundo* seed in the treatment of primary dysmenorrhoea is quite efficacious. Thus, this study validated the medicinal treatment recommended by Unani practitioners in the treatment of primary dysmenorrhoea.

In this study *Vitex negundo* is almost as effective as Combiflam. According to Najmul Ghani, *Tukhm-e-Sambhalu* cures all menstrual problems[19]. The effect of *Sambhalu* (*Vitex negundo*) was owing to its *musakkin* (anodyne), *mohallil* (anti-inflammatory)[17], *daf-e-alam* (analgesic), *moarrique* (diaphoretic)[19], *mudirr-e-haiz* (emmenagogue) and *musakhkhin* (calorific) properties[16]. It is also pharmacologically proved for analgesic effects and action on central nervous system[20], anti-nociceptive[21], anti-inflammatory[22], deobstruent[23], diuretic, emmenagogue, nerve tonic[24], analgesic and tranquillizing effects (Anonymous, 1976). Tandon and Gupta states that prostaglandin inhibition and reduction of oxidative stress are responsible for analgesic effect and this is not mediated through opioid receptors[21]. Telang *et al.* explained that

Table 2 — Effect of drug on clinical features

Clinical features	Group I (Standard Control)						Group II (Test)					
	Baseline		Post Treatment		Improvement		Baseline		Post Treatment		Improvement	
	N	%	N	%	N	%	N	%	N	%	N	%
Pain in suprapubic region	30	100	11	36.66	19	63.33	30	100	16	53.33	14	46.66
Pain in thigh	24	80	08	33.33	16	66.66	26	86.66	11	42.33	15	57.69
Backache	23	76.66	05	21.73	18	78.26	26	86.66	11	42.30	15	57.69
Headache	05	16.66	00	00	05	100	03	10	00	00	03	100
Nausea / vomit	02	6.66	01	50	01	50	04	13.33	01	25	03	75
Syncope	01	3.33	00	00	01	100	02	6.66	01	50	01	50

prostaglandin synthesis inhibition of fresh leaves attributed anti-inflammatory and pain suppressing activities [26]. An aqueous extract of the fruits of *Vitex negundo* found to have good analgesic action, when tested on rats, by analgesiometric method[25].

In the pathogenesis of dysmenorrhoea, prostaglandin (PG) and arachiodonic acid metabolites have an important role [6]. The menstrual cramps intensity and dysmenorrhoea's associated symptoms are directly proportional to the released quantity of PGF2 α. During first two days of menstruation maximum amount of prostaglandin is released, that is equal to time of maximum discomfort[14]. Prostaglandins are recognized to increase the contraction of myometrium and also small endometrial blood vessels constrictionsthat produces endometrial ischemia and its breakdown leads to bleeding and pain. Increase of Prostaglandin E2 level increases the nerve endings sensitivity to pain[12]. The pain is usually associated with prostaglandin. Women suffering from this pain have higher concentration of PGF2 in menstrual blood. PGE2 causes uterine concentration, cervical narrowing, increase in vasopressin release which causes ischemia and pain. Thus, suppression of PG production cures the problems[6]. Although in Unani literature the exact mechanism of action has not been explained but the pharmacological activities expressed in Unani medicine have been validated by various researchers suggesting that the basis of therapy as explainedin classical literature of Unani medicine is in conformity with the scientific reports of recent studies. Therefore, the mechanism of action proposed in scientific studies[6,14] may be the pharmacological basis of efficacy of test drug in cases of dysmenorrhoea.

Conclusion

It can be concluded in the light of above results and discussion, that seeds of *Vitex negundo* (*Tukhm-e-Sambhalu*) possess significant level of efficacy in *Usr-e-Tams Ibtedayee* (primary dysmenorrhoea), that is mentioned in ethno-botanical and classic Unani literature. It may be used effectively in patients affected with primary dysmenorrhoea. It is also observed that it is well tolerated by the patients without having any type of side effects. Therefore, this study scientifically authenticates the therapeutics application of *Vitex negundo* seed in cases of primary dysmenorrhoea. However, for further research more elaborative and extensive studies should be done for the exact mechanism of action of the test drug.

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